EXHIBIT D

Ver 5

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TO: Kevin Thurm
Deputy Secretary
Through: ES_____
COS_____

FROM: Michael M. Hash
Deputy Administrator

SUBJECT: Use of Department of Justice (DOJ) Data in Pricing of Drugs Currently Covered by Medicare -- INFORMATION

Issue We have been considering options for using the alternative average wholesale price (AWP) data provided by DOJ. While we believe that Medicare overpays for the drugs identified by DOJ, we also must assure continued beneficiary access to these drugs. Per your request, we have met with physician and provider groups who furnish Medicare beneficiaries with the drugs on the DOJ list, and conducted some impact analyses. A dilemma arises from the fact that delivery systems have developed around overpriced drugs. Reductions in the reimbursement, particularly in the magnitude contemplated by the DOJ, could disrupt these systems of care. As you know, we have received Congressionals both to release these drug prices and to take no action. In sum, we plan to release the data -- carriers can choose to use it, except for data on chemotherapeutic and hemophilac drugs. We also plan to delay the impact until January 1, 2001, and pursue legislative proposals this fall addressing some of the administrative cost concerns. This memo presents the strategy we plan to pursue.

Background We recently met with organizations representing: oncologists; urologists; the end-stage renal disease community; hemophilia suppliers; and suppliers of asthma equipment/drugs and home infusion therapy, to discuss their concerns about our use of the DOJ alternative AWP data as a basis for determining Medicare's outpatient drug allowances (which are currently based on 95 percent of the AWP). Attachment A provides a brief summary of the concerns raised by these organizations, some of our countervailing concerns, and estimated savings if the DOJ data would be implemented.

These organizations argued that: 1) a high profit margin on drugs is necessary to cross-subsidize costs that are underfunded, such as drug administration; 2) beneficiaries would have limited access, as they would possibly have to receive care in more costly, less convenient settings; 3) quality of care could deteriorate, since the DOJ list does not cover all drugs and there would be substitution of potentially less effective drugs for which the inflated payment could still be obtained; 4) there is insufficient time and information to successfully implement the change, and the policy was announced without adequate comment from stakeholders -- a transition period was seen as critical; and 5) in exploring an option to pay for drugs based on acquisition costs, there was a view that acquisition

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costs should include an adjustment for spillage and additional paperwork, and there should not be a national limit, such as the median actual acquisition costs in Medicare in a prior year.

While some of the arguments raised by these organizations appear to have merit, we do not think it is clear in every case made that Medicare payment is inadequate to cover drug administration costs, and that access and quality of care would suffer if we implement the DOJ data. Also, we can not loose sight of the fact that lower drug payments would result in lower cost-sharing and Part B premiums for beneficiaries. We continue to believe that Medicare payment for outpatient drugs is excessive; and that our payment systems should be calibrated to pay correctly for covered drugs and for delivery of those drugs.

Medicare carrier payments in 1999 for the approximately 50 drugs on the DOJ list totaled roughly $1.8 billion. If carriers were to fully use the DOJ data immediately, instead of the AWP data from the *Red Book* (the source used by all by one carrier), full year savings of roughly $650 million would be achieved. However, this savings estimate needs to be reduced because of substitute drugs that are not on the DOJ list, and due to the effect of lowering Medicare drug prices through an administrative action (rather than through a statutory or regulatory change) on the sustainable growth rate system (SGR). This would allow physicians, rather that the Medicare program or beneficiaries, to receive the savings from drug price reductions through higher future physician fee schedule updates.

Plan of Action and Timeline In our desire to calibrate our payment systems to correct high Medicare drug payments and to adjust payments as may be needed for delivery of those drugs, we plan to pursue a two part policy strategy to address both. Our strategy would:

- Send to Medicare carriers the DOJ data for all drugs. Instruct carriers not to implement the DOJ data for oncology and hemophilia drugs at this time while we consider related Medicare payment policies which could affect access for beneficiaries. Carriers would determine what, if any, of the DOJ data for the remaining drugs should be used. Delay the effective date until January 1, 2000 to provide more time for necessary systems changes and transitioning. Require carriers to assess access to the drugs and report to us in November on the data source they use for setting Medicare drug allowances.

- Submit legislation in September to set Medicare prices at the Average Manufacturers Price (AMP) plus a reasonable mark-up. We believe that instead of proposing to base Medicare payment on actual acquisition costs, we should propose AMP plus a reasonable mark-up. AMP is auditable and we currently have and use it in computing Medicaid drugs rebates.

- Submit legislation in September for targeted fixes in policies related to the provision of drugs which could not be addressed administratively. Such legislation would include increasing the ESRD composite rate, increasing payments for chemotherapy administration and establishing a hemophilia administration fee for certain entities.

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Submit legislation to reduce the physician SGR target by the amount of savings estimated to be achieved.

We would convey these plans through a Program Memorandum (PM) that will be released in late August or early September. This approach would be consistent with the commitment to Chairman Bliley. Exempting oncology and hemophilia drugs would focus on the drugs representing about 70 percent of the savings. Delaying until January would provide time for system changes and transition as well as time for carriers to assess access at the local level and report their findings to us. While, access problems for oncology and hemophilia drugs seem most compelling, it may be difficult to explain why the DOJ data are more accurate, but we are not implementing them for certain drugs at this time. As a result, there might be legal challenge. However, we would consider putting oncology and hemophilia drugs back on the table if legislation we propose on related policies were adopted.

We plan to prepare a letter to Congress and to meet with inquiring members when the PM is released, to explain our policy response to the DOJ data and recommendations.

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Attachment A

We recently met with organizations representing: oncologists; urologists; the end-stage renal disease community; hemophilia suppliers; and suppliers of asthma equipment/drugs and home infusion therapy. Based on our discussions with the groups and our analysis, the following major issues exist in using the DOJ data.

Cross-Subsidies. Notably, the groups generally agreed that these drugs could be obtained at the lower DOJ AWP levels. However, some groups indicated that the DOJ levels would be below their costs in certain situations. The groups generally argued that they needed to "profit" on their Medicare drug payments in order to compensate or "cross-subsidize" Medicare payments related to other aspects of provision of the service that they claim are either inadequate or not covered at all.

For example, oncologists argued that their Medicare drug profits cross-subsidize what they believe are inadequate Medicare payments for chemotherapy administration. About two-thirds of their Medicare revenues comes from drugs, and less than 10 percent is from chemotherapy administration. Similarly, hemophilia centers argued that since payment for drugs is the only payment they receive from Medicare, they use their Medicare drug profits to cover administration of drug. Providers of home infusion and asthma care argued that their Medicare drug profits were used to cover related services such as checking that the patient has an appropriate supply of drugs and is following the prescribed regime. This latter case was less compelling than others, as it is unclear that payment for these services is not included in Medicare's current payment for the equipment itself and equipment servicing fees.

ESRD facilities argued that their Medicare drug profits are used in part to compensate for cost-sharing bad-debts. They claim to experience a disproportionate share of bad-debt relative to other providers, and point out that Medicare recognizes bad-debt for other facilities.

Access to Care. All the groups expressed concern that beneficiaries would possibly have to receive their care in more costly, less convenient settings, such as hospital outpatient departments (e.g., chemotherapy) or emergency rooms (e.g., hemophilia or respiratory therapy). Oncologists argued that if they lost their Medicare drug profits, they could not cross-subsidize inadequate chemotherapy administration payments and would have to shift care from the office setting into hospitals and outpatient clinics. This could be more of a problem in rural settings where beneficiaries could face increased travel time and expenses. Apria, a company which furnishes home infusion and asthma care, reported a recent decision to refuse new Medicaid patients in twelve states when the DOJ data were implemented for Medicaid through First Data Bank.

Quality of Care. Groups expressed concern about two aspects of quality of care. First, since the DOJ list does not cover all drugs, there would be substitution of alternative and potentially less effective drugs for which the inflated payment could still be obtained. For example, there could be substitution of plasma-generated Factor IX for recombinant-

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generated Factor IX, which is the drug of choice for beneficiaries with HIV.

Second, some groups argued that there would be deterioration in quality controls and related support services that are not covered. An example is the provision of Albuterol without intermittent monitoring of the beneficiary to ascertain if they are actually taking their respiratory treatments, and checking refill prescriptions against physician orders that may have been revised or having a 24-hour capacity for access to respiratory therapists if the need should arise. However, we are concerned that some of these additional services might be used more as marketing devices than as patient quality controls.

Operational Constraints and Transition. Groups expressed concern that there was insufficient time and information to successfully implement the change. Some groups complained that the policy was announced without adequate comment from stakeholders, and that significant reductions in prices could even possibly violate the law under this circumstance.

A longer lead-time than October 1, 2000 and a transition period were seen as critical to assure access to care and avoid confusion among providers and beneficiaries. Some groups pointed to the need to renegotiate contracts, make systems changes, and plan for the anticipated reductions in revenue.

Actual Acquisition Costs: We also heard concerns about basing Medicare payment for drugs on actual acquisition costs. There was a view that acquisition costs should include an amount for spillage, storage and taxes, and for paperwork to determine actual acquisition costs for drugs net of discounts. Also, there was concern that our prior legislative proposal had a national limit, i.e., our payment of actual acquisition costs was subject to a limit of the median actual acquisition costs in Medicare in a prior year.

Savings Estimates and Impact Analysis. Medicare carrier payments in 1999 for the approximately 50 drugs on the DOJ list totaled roughly $1.8 billion. If carriers were to fully use the DOJ data immediately, instead of the AWP data from the *Red Book* (the source used by all by one carrier), full year savings of roughly $650 million would be achieved. (This is not an actuarial estimate and savings could be lower given assumptions about a variety of slipages). The savings occur because *Red Book* AWPs are neither an average nor a wholesale price, but rather a manufacturer's list price whereas the DOJ data reflect prices from wholesaler catalogs. Where savings are generated, beneficiaries will benefit from lower cost-sharing and Part B premium payments.

However, this savings estimate needs to be reduced because of substitute drugs that are not on the DOJ list. Approximately three-quarters of carriers have implemented a least costly alternative policy that reduced the price of Lupron to the price of Zoladex, which is still less expensive than the DOJ price for Lupron. Albuterol also has substitutable drugs not on the DOJ list.

Savings also need to be considered in the context of the physician sustainable growth rate system (SGR). Medicare spending for some certain drugs (representing approximately

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half of the DOJ savings) are included in the measurement of performance under the SGR. Lowering Medicare payment for these drugs through administrative action (rather than through a statutory or regulatory change) would diminish savings going to the Medicare program and to beneficiaries, because physicians would receive the savings through higher future physician fee schedule updates. (This problem could be resolved by with a legislative fix.)

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DOJ AMP v. AWP Drug Pricing Comparison Data

	HCPCS	New HCPCS	NDC	AMP	BP	98 Red Book	AMP/RedBk
Etoposide	J9182		00074 1485 48	No Info Found			#VALUE!
EPO	Q0136		55513 0126 10	$19.48	$16.66	$24.00	81.2%
Lupron	J9217		00300 3629 01	$429.79	$170.00	$540.63	79.5%
	J2430		00083 2601 04	$172.62	$156.10	$218.24	79.1%
	J1626		00029 4149 01	$139.08	$80.00	$177.40	78.4%
Leucovorin	J0640		00641 2369 41	$43.98		$56.25	78.2%
Paclitaxil	J9265		00015 3475 30	$28.34	$21.33	$36.53	77.6%
	J9045		00015 3213 30	$72.39	$69.45	$93.46	77.5%
Zoladex	J9202		00310 0960 36	$246.12	$167.48	$439.24	56.0%
	J1561		00944 2620 01	$27.44	$23.10	$54.92	50.0%
Gama Globuli	J1562		00026 0648 20	$3.31	$2.92	$9.00	36.8%
	K0518	J7644	49502 0685 03	$0.240825		$0.71	34.1%
Doxorubicin	J9000		00013 1136 91	$3.09	$1.34	$10.24	30.2%
Albuterol	K0505	J7619	49502 0697 03	$0.083228	$0.009155	$0.40	20.6%

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	HCPCS Code(s)	HCPCS Description	Total Allowed Charges	Percentage AWP to Red Book	Total Dollars Saved
1	J9040	Bleomycin sulfate injection	$2,678,439	-32.5%	($869,254)
1	J9060	Cisplatin 10 MG injeciton	$7,434,950	-32.0%	($2,382,748)
1	J9062	Cisplatin 50 MG injeciton	$10,363,407	-32.0%	($3,321,292)
1	J9091	Cyclophosphamide 1.0 grm inj	$690,165	-64.1%	($442,256)
1	J9070	Cyclophosphamide 100 MG inj	$1,568,915	-64.1%	($1,005,305)
1	J9092	Cyclophosphamide 2.0 grm inj	$116,166	-64.1%	($74,435)
1	J9080	Cyclophosphamide 200 MG inj	$210,512	-64.1%	($134,889)
1	J9090	Cyclophosphamide 500 MG inj	$691,520	-64.1%	($443,101)
1	J9097	Cyclophosphamide lyophilized	$417,095	-56.5%	($235,742)
1	J9096	Cyclophosphamide lyophilized	$1,524,257	-56.5%	($861,510)
1	J9095	Cyclophosphamide lyophilized	$1,095,089	-56.5%	($618,944)
1	J9094	Cyclophosphamide lyophilized	$392,854	-56.5%	($222,041)
1	J9093	Cyclophosphamide lyophilized	$2,174,036	-56.5%	($1,228,765)
1	J9100	Cytarabine hcl 100 MG inj	$330,505	-53.0%	($175,146)
1	J9110	Cytarabine hcl 500 MG inj	$168,504	-53.0%	($89,292)
1	J1260	Dolasetron mesylate	$46,647,272	-44.5%	($20,766,281)
1	J9000	Doxorubic hcl 10 MG vl chemo	$27,831,805	-84.1%	($23,406,989)
1	J9181	Etoposide 10 MG inj	$7,971,562	-91.4%	($7,286,982)
1	J9182	Etoposide 100 MG inj	$15,290,199	-91.4%	($13,977,202)
1	J9190	Fluorouracil injection	$3,741,974	-56.4%	($2,111,901)
1	J1626	Granisetron hydrochlor/100 mcg	$46,432,246	-25.3%	($11,764,258)
1	J0640	Leucovorin calcium injection	$66,740,227	-85.9%	($57,319,561)
1	J9260	Methotrexate sodium inj	$1,150,850	-51.0%	($586,823)
1	J9250	Methotrexate sodium inj	$275,325	-51.0%	($140,396)
1	J2405	Ondansetron hcl injection	$47,721,885	-32.7%	($15,616,369)
1	J9360	Vinblastine sulfate inj	$608,183	-75.2%	($457,132)
1	J9370	Vincristine sulfate 1 MG inj	$2,536,861	-87.3%	($2,214,338)
1	J9375	Vincristine sulfate 2 MG inj	$1,361,596	-86.3%	($1,174,377)
1	J9380	Vincristine sulfate 5 MG inj	$52,272	-86.3%	($45,085)
2	Q0160	Factor IX non-recombinant	$3,130,782	-31.0%	($971,622)
2	Q0161	Factor IX recombinant	$7,690,671	-31.0%	($2,386,760)
2	J7190	Factor viii	$30,832,294	-32.7%	($10,093,213)
2	J7192	Factor viii recombinant	$49,063,100	-33.0%	($16,208,346)
3	J7610	Acetylcysteine 10% inhalation	$2,146	-55.8%	($1,198)
3	J7615	Acetylcysteine 20% inhalation	$32	-55.8%	($18)
3	K0503	Acetylcysteine inh sol u d	$35,908,222	-55.8%	($20,040,379)
3	K0504	Albuterol inh sol con	$3,356,397	-67.7%	($2,271,136)
3	K0505	Albuterol inh sol u d	$246,136,877	-67.7%	($166,524,613)
3	J7620	Albuterol sulfate .083% inh	$13,539	-67.7%	($9,160)
3	J7625	Albuterol sulfate .5% inh	$12,477	-67.7%	($8,441)
3	K0511	Cromolyn sodium inh sol u d	$2,965,592	-45.5%	($1,348,285)
3	J7630	Cromolyn sodium inhalaton	$130	-45.5%	($59)
3	J7670	Metaproterenol sulfate .4%	$737	-63.3%	($466)
3	J7672	Metaproterenol sulfate .6%	$84	-63.3%	($53)
3	J7675	Metaproterenol sulfate 5%	$23	-63.3%	($15)
4	J1950	Leuprolide acetate /3.75 MG	$1,166,135	-19.6%	($228,051)
4	J9218	Leuprolide acetate inj	$45,931	-19.6%	($8,983)
4	J9217	Leuprolide acetate suspnsion	$620,102,889	-19.6%	($121,270,840)

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4	J9290	Mitomycin 20 MG inj	$3,651,955	-66.7%	($2,435,417)
4	J9291	Mitomycin 40 MG inj	$9,755,500	-66.7%	($6,505,817)
4	J9280	Mitomycin 5 MG inj	$2,434,904	-66.7%	($1,623,806)
5	J0635	Calcitriol injection	216,179,667	-19.1%	($41,320,514)
5	J1780	Iron dextran 10 CC inj	187,825,227	-34.5%	($64,837,268)
5	J1760	Iron dextran 2 CC inj	14,428,784	-34.5%	($4,980,816)
5	J1770	Iron dextran 5 CC inj	$388,933	-34.5%	($134,260)
6	J0286	Amphotercin B inj 50 MG, lipid	$970,000	-50.9%	($493,268)
6	J0285	Amphotercin B injection 50 MG	$468,965	-50.9%	($238,480)
6	J7070	D5w infusion	$660,605	-80.8%	($533,503)
6	J1095	Dexamethosone acetate 8 MG	$1,069,618	-81.3%	($869,653)
6	J1100	Dexamethosone sodium phos	$3,625,998	-54.1%	($1,961,302)
6	J7042	Dextrose/normal saline 5%	$1,125,207	-82.4%	($926,717)
6	J7060	Dextrose/water 5%	$2,459,708	-80.8%	($1,987,268)
6	J3360	Diazepam injection	$77,654	-63.4%	($49,255)
6	J1940	Furosemide injection	$170,987	-82.0%	($140,272)
6	J1580	Garamycin gentamicin inj	$311,988	-81.5%	($254,298)
6	J1642	Heparin sodium per 10 u inj	$3,950,275	-73.7%	($2,911,477)
6	J1644	Heparin sodium per 1000u inj	$495,337	-73.7%	($365,079)
6	J1720	Hydrocortisone sodium succi	$88,153	-60.6%	($53,378)
6	J1562	Immune globulin 10% /5 grams	$43,239,398	-19.1%	($8,270,216)
6	J1561	Immune globulin injection	$46,742,094	-19.1%	($8,940,444)
6	J2060	Lorazepam injection	$503,102	-66.9%	($336,373)
6	J1020	Methylprednisolone 20 MG inj	$136,604	-59.4%	($81,074)
6	J1030	Methylprednisolone 40 MG inj	$2,416,108	-59.4%	($1,433,960)
6	J1040	Methylprednisolone 80 MG inj	$3,755,325	-59.4%	($2,228,785)
6	J2930	Methylprednisolone injection	$763,014	-67.0%	($511,213)
6	J2920	Methylprednisolone injection	$193,816	-67.0%	($129,857)
6	J2545	Pentamidine isethionte/300mg	$208,045	-85.3%	($177,370)
6	J2792	Rho(D) immune globulin h, sd	$4,244,766	-53.3%	($2,262,733)
6	J2912	Sodium chloride injection	$749,285	-82.7%	($619,821)
6	J1060	Testosterone cypionate 1 ML	$94,124	-44.6%	($41,989)
6	J1090	Testosterone cypionate 50 MG	$10,588	-44.6%	($4,723)
6	J3130	Testosterone enanthate inj	$96,614	0.0%	$0
6	J3120	Testosterone enanthate inj	$12,295	0.0%	$0
6	J0900	Testosterone enanthate inj	$6,426	0.0%	$0
6	J3260	Tobramycin sulfate injection	$137,576	-59.8%	($82,227)
6	J3370	Vancomycin hcl injeciton	$680,916	-55.6%	($378,881)
7	S0071	Acyclovir Sodium	$0	-49.3%	$0
7	S0072	Amikacin Sulfate	$0	-58.9%	$0
7	S0023	Cimetidine Hydrochloride	$0	-86.4%	$0
7	S0077	Clindamycin Phosphate	$0	0.0%	$0
			$1,852,776,290	Totals	($668,465,565)

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Specs for Legislation for Policies *Related* to the Use of DOJ AWP Data

(1) ESRD Facility Drugs. In addition to the 1.2 percent increase that BBRA increased the composite rate for 2001, and on top of the additional 1.2 percent increase for 2001 that the Administration proposed in June, we would propose legislation to further increase the ESRD composite rate by 3 percent for 1/1/01 (the precise increase needs to be examined further). Thus the composite rate would be increased in 2001 by a total of 5.4 percent. The amount of the 3 percent additional increase would be approximately equal to the estimated savings from ESRD facilities that would occur by using the DOJ data. Because of our concern with how the changes would affect ESRD facilities, propose a study and report to Congress on ESRD facility profitability, including Medicare revenues for items and services excluded from the composite rate, and growth in the supply of facilities.

(2) Hemophilia Drug Administration Fee. Propose to require the Secretary to establish, by 4/1/01, a fee to be paid to entities that administer drugs to hemophilia patients. Should the proposal apply to whomever administers the drugs or apply only to certain types of entities which furnish the drugs? Should the fee be limited to administration of factor drugs or would it also apply to any other drugs administered? Would the administration fee be subject to normal Part B cost-sharing?

(3) Oncology Drugs. Propose legislation to increase the oncologists chemotherapy administration fee by an amount equal to their current aggregate Medicare drug profits (that would be eliminated by using the DOJ data). Because some of the increased chemotherapy administration fees would pay physicians more to provide chemotherapy in their offices than in hospital outpatient departments, the increased physician office chemotherapy administration fees would be limited to the OPD PPS rates for chemotherapy administration. Because of desire to create a level playing field between physician offices and OPDs, propose to lower OPD coinsurance for chemotherapy administration to 20 percent on 1/1/02.

(4) SGR Related Amendment. Since the DOJ AWP policy would be accomplished by administrative action rather than by a change in law or regulation, propose legislation to reduce the physician sustainable growth rate (SGR) target by the amount of the drug savings estimated to be achieved. This would apply to drugs included in data used to determine SGR performance (e.g., incident to drugs), but exclude drugs furnished as part of the durable medical equipment benefit or drugs furnished by ESRD facilities. This proposal would assure that the Medicare program and Medicare beneficiaries achieve the savings, rather than having the savings result in an increase in the update for all physicians.

Specs for Legislation for Payment of Currently Covered Medicare Drugs

Propose legislation, effective 7/1/01, to use the average manufacturers price (AMP), currently available to the Secretary for determining Medicaid drug rebates, plus a reasonable mark-up as the payment basis for currently covered Medicare drugs.

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Directory:		
Server:	HCFABPD2	
Queue:		
Printer:	!LEX03FB4D_INT	
Description:	ChromaSound FAQ	
Submitted:	May 19, 1999	8:16:12 am
Printed:	May 19, 1999	8:16:15 am

XL02

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HHC902-0233

X Comms

Robin Felitti

- Operational issue for providers (Timing)

Drug markup ⇒ Cross-Subsidize

Quality/Access ⇒ refer to ERs

Drug Substitutions

- Savings not net C - LCA; drug substitution

- Lead Time from providers + Contractors

Options

- Oct vs. Jan
- Carriers have discretion

OCT or Jan

- Pick & choose
- Delay til Jan 1 + A-19

---

1 - Do nothing - Retreat
w/ A-19 more complicated drug TOPPS
Do a reg

2 - Minimal
- Delay Jan 1 - Systems, notification
- Consider it in AWP Carrier discretion - give date to carriers
- + A-19 Do a reg

4 - Blends Red BK + DOT 3 - Pick & choose based on Access
2 ways Knowing legal challenge
Clear instructions for Jan
50-50 blend
Bad precedent

8/10 Draft AWP Workplan

Due Date	Task	Product	Lead/Support
8/7 8/12	Notify Dep Sec of NAMD decision (made 8/2)	1) Info memo to OA 2) Meeting	Lead: CHPP (TDecaro) Support: GC, OL, CMSO, CBS, OIS Lead: OA (PHarbage)
	Policy Development:		
8/11 8/18 Effect Date ??	1) Oncology PE (admin chg. Rerunning numbers?)	1a) Briefing paper 1b) Decision memo 1c) Other?	Lead: CHPP (TKay) Support: GC, OL, CBS, OIS
8/11 8/18 Effect Date??	2) Oncology admin overhead costs (statutory fix)	2a) Briefing paper 2b) A-19?	Lead: CHPP (TKay) Support: GC, OL
8/11 8/18 Effect Date ??	3) Hemophilia admin fee (statutory fix)	3a) Briefing paper 3c) Other?	Lead: CHPP (TKay) Support: GC, OL
8/11 8/18 Effect Date ??	4) ESRD composite rate (statutory fix)	4a) Briefing paper 4c) A-19	Lead: CHPP (THoyer) Support: GC, OL, CBS, OIS
8/11 8/18 Effect Date ??	5) Average Manufacturers Price (AMP) w/ markup (statutory fix)	5a) Briefing paper 5b) A-19	Lead: CHPP (BNiemann) Support: GC, OL, CMSO
	6) Other		
8/11	6a) Albuterol in Texas DME demo	6a) Briefing paper	Lead: CHPP (SArnold)
8/11	6b) Other agency experience/issues w/ AWP & other pricing strategies	6b) Briefing paper	Lead: CHPP (BNiemann) Support: CMSO (LReid)

HHC902-0235

8/25? 8/29 Carrier feedback: 11/1/2000 Effective Date (DOJ data): 1/1/2001	Instruct carriers: -- on use of DOJ data -- to report on current sources and use of data to set drug allowances, and on information they have about access to drugs on DOJ list	1a) PM clearance finished 1b) PM release (see rollout below)	Lead: CHPP (BNiemann) Support: GC, OL, CMSO, CBS, OIS Clear thru Change Management process? Lead: CBS? Support: CHPP, GC, OL, CMSO, OIS

8/18 8/25	Prep for Rollout of PM on DOJ AWP data	Finalize: ■ Press release ■ clear w/ dept?	Lead: OL, Press Office Support: CHPP, CMSO, CBS
8/18 8/25	Letter to Congress about AWP and leg proposals under consideration	■ Prepare ■ Clear w/ dept?	
8/21 -- 8/25		■ Q&As	
8/21 – 8/25		■ Talking points	
	Coordination of rollout		Lead: OA (PHarbage) Support: CHPP, OL, Press Office, CMSO
Rollout: 8/29	Contacts: 1) Release PM	1a) Send 1b) Post on web	Lead: CBS
8/21 8/24 – 25	2) Department	2a) Briefings w/ Assoc Dirs (e.g., Claxton) 2b) Brief Dep Sec	Lead: OA (PHarbage), w/ CHPP, OL, Press Office
8/21 8/28 -30	3) OMB	3) Briefings	Lead: CHPP
8/29	4) Hill	4a) Letter to Congress 4b) Briefings	Lead: OL w/ CHPP
8/29	5) Providers	5a) Notice/Calls to affected associations 5b) Other?	Lead: CHPP
8/29 8/29 - 30	6) Benes	6) Notice/Calls to advo	Lead: CBS
	7) Public/Press	7) ??	Lead: Press Office

HHC902-0237

(2) Hemophilia Drug Fee. The current provision in the law for hemophilia drugs is:

1861(s)(2)(I)
blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

We would propose to add the following to be effective April 1, 2001:

blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, ~~and~~ items related to the administration of such factors, ***and costs incurred by suppliers of such factors such as shipping, storage, inventory control, billing and other costs as specified by the Secretary,***
subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

We are currently obtaining data to show the allowed charges per beneficiary per month for these factors. We have been old that it is $10,000-20,000 per month. The DOJ prices represent about a 30 percent reduction. The cost that I have not specified is "profit margin" to make this business worth doing for Medicare beneficiaries.

Q. Should the proposal apply to whomever administers the drugs or apply only to certain types of entities which furnish the drugs?

ANS. It should be tied to the supplier of the drugs. I think the possibility of creating a new class of provider for medical support services and home administration goes far beyond the immediate problem and should be given much more study. (e.g., certification, scope of services)

Q. Should the fee be limited to administration of factor drugs or would it also apply to any other drugs administered?

A. The additional coverage would not be for "administration"; these factors are by and large self-administered in the home. The additional coverage would be for overhead expenses and provide the program with a basis to pay some profit margin to the supplier.

Q. Would the administration fee be subject to normal Part B cost-sharing?

A. Yes. There is still a need for utilization control as recognized by the current statute. Furthermore, there should be cost sharing by the beneficiary where it is available.

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Submitted:	May 21, 1999 2:19:38 pm
Printed:	May 21, 1999 2:19:42 pm

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DOJ Drug Pricing Comparison Data - August 8, 2000

DOJ AMP v. AWP Drug Pricing Comparison Data

	HCPCS	New HCPCS	NDC	AMP	BP	98 Red Book	
	J9217		00300 3629 01	$429.79	$170.00	$540.63	79.5%
	K0505	J7619	49502 0697 03	$0.083228	$0.009155	$0.40	20.6%
	J9202		00310 0960 36	$246.12	$167.48	$439.24	56.0%
	K0518	J7644	49502 0685 03	$0.240825		$0.71	34.1%
	J9265		00015 3475 30	$28.34	$21.33	$36.53	77.6%
	Q0136		55513 0126 10	$19.48	$16.66	$24.00	81.2%
	J0640		00641 2369 41	$43.98		$56.25	78.2%
	J9045		00015 3213 30	$72.39	$69.45	$93.46	77.5%
	J1626		00029 4149 01	$139.08	$80.00	$177.40	78.4%
	J1562		00026 0648 20	$3.31	$2.92	$9.00	36.8%
	J9182		00074 1485 48	No Info Found			#VALUE!
	J9000		00013 1136 91	$3.09	$1.34	$10.24	30.2%
	J1561		00944 2620 01	$27.44	$23.10	$54.92	50.0%
	J2430		00083 2601 04	$172.62	$156.10	$218.24	79.1%

Lupron
Aldt
Zoladex

Procrit
EPO
Levaquin

Gamma Glob
Etopside
Doxorubicin

User Name:	XL02
File Name:	
Directory:	
Server:	HCFAFHR5
Queue:	
Printer:	ILEX0342E2_INT
Description:	C:\OFFICE\WPWIN\WPDOCS\AMBUL\PARA-INT\HCF1813.429
Submitted:	May 3, 1999 8:09:40 am
Printed:	May 3, 1999 8:09:43 am

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LPT3

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HHC902-0242

Clotting factor 1999 - 5% Sample

#Months	$Avg_Month	$Annual	$Annual
2	97,048	194,096	267,180
5	53,436	267,180	257,076
5	51,415	257,076	214,471
4	49,892	199,568	199,568
2	45,693	91,386	194,096
1	36,816	36,816	185,684
3	30,689	92,068	184,984
6	28,440	170,640	182,703
4	27,093	108,371	170,640
7	26,100	182,703	166,812
4	24,146	96,584	108,371
4	21,510	86,039	103,447
2	21,206	42,413	96,584
9	20,632	185,684	95,417
9	20,554	184,984	92,068
5	18,165	90,825	91,386
12	17,873	214,471	90,825
10	16,681	166,812	86,039
6	15,903	95,417	63,340
4	15,835	63,340	56,188
2	14,363	28,727	45,400
4	14,047	56,188	42,413
3	12,504	37,512	37,512
10	10,345	103,447	36,816
2	9,362	18,724	32,166
5	9,080	45,400	28,727
1	8,352	8,352	18,724
2	7,392	14,784	14,784
1	7,000	7,000	13,095
2	6,548	13,095	8,352
6	5,361	32,166	7,000
1	5,262	5,262	5,262
1	3,724	3,724	3,724
1	2,155	2,155	2,155
	22,195	Avg	
145	22,090	Wtd Avg	

91,515 Avg_Patient

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Directory:	
Server:	HCFAFHR5
Queue:	
Printer:	ILEX0342E2_INT
Description:	C:\OFFICE\WPWIN\WPDOCS\AWP-A19.WPD
Submitted:	April 30, 1999 2:50:09 pm
Printed:	April 30, 1999 2:50:15 pm

XL02

LPT3

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HHC902-0244